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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0318]

Guidance for Industry: Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Industry: Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products.'' The guidance document is intended to provide recommendations to all registered blood and plasma establishments and all establishments engaged in manufacturing plasma derivatives. The guidance document is intended to replace the FDA guidance entitled ''Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) by Blood and Blood Products'' issued on December 11, 1996.

DATES: Written comments may be submitted at any time, however, comments should be submitted by (*insert date 60 days after date of publication in the* **Federal Register**), to ensure adequate consideration in preparation of a revised document, if warranted. The agency is soliciting public comment, but is implementing this guidance document immediately because of the public health concerns related to the possible risk of transmission of CJD and nvCJD by blood and blood products.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Guidance for Industry: Revised Precautionary Measures to Reduce the Possible Risk of

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Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document entitled ''Guidance for Industry: Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products.'' The guidance document is intended to replace the FDA guidance entitled ''Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) by Blood and Blood Products'' sent by mail to blood and plasma establishments and plasma derivatives manufacturers on December 11, 1996. See notice of availability (62 FR 49694, September 23, 1997).

Recommendations addressed in the guidance document include: (1) Donor screening questions and deferral criteria, (2) disposition of implicated products, (3) consignee notification and recipient counseling, and (4) product labeling.

The guidance document represents the agency's current thinking on precautionary measures to reduce the possible risk and to assure that blood and blood products are not adulterated or misbranded, within the meaning of the Federal Food Drug and Cosmetic Act, and are safe, pure and potent within the meaning of the Public Health Service Act. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The guidance document is intended to provide information and does not set forth requirements.

II. Comments

The agency is soliciting public comment, but is implementing this guidance document immediately because of the public health concerns related to the possible risk of transmission of CJD and nvCJD by blood and blood products. Additionally, the guidance presents a less burdersome policy for the management of blood components and plasma derivatives in cases where the donor has classic CJD or CJD risk factors. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this guidance document. Written comments may be submitted at any time, however, comments should be submitted by (*insert date 60 days after date of publication in the* **Federal Register**), to ensure adequate consideration in preparation of a revised document, if warranted. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance document and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance document using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: 8/4/99
August 4, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Margaret M. Dotzel
Acting Associate Commissioner for Policy

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